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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,341	11/20/2006	Guido Rasi	2697-119	4578
6449 7590 09/28/2009 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER				
KOSAR, ANDREW D				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
09/28/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

### Office Action Summary

**Application No.**

10/551,341

**Applicant(s)**

RASI ET AL.

**Examiner**

ANDREW D. KOSAR

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 8/11/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendments/Arguments***

Applicant's amendments and arguments filed June 25, 2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant has amended the claims to recite the prevention is in an immunocompromised host. Applicant argues that none of the references (Chretien, Goldstein, Knutsen and Rudolph) teach prevention/treating *Aspergillus* infections nor do they discuss *Aspergillus* infections or a connection between the administration of TA1 for the diseases presented and *Aspergillus*. Applicant further argues that the combination of references does not render the instant claims obvious; asserting that amphotericin B was taught to treat/prevent fungal infections and that there is no express teaching that TA1 does so.

Respectfully, TA1 was administered to immunocompromised patients, and thus necessarily acted to prevent *Aspergillus* infections. The antifungal activity of TA1 is an inherent property, and the property cannot be separated from the compound. Thus, even though the art may have administered for a different purpose, e.g. treating HCV, sepsis, etc.- all patient populations which are immunocompromised- it inherently is preventing *Aspergillus* infections. With regards to the obviousness, the combination of TA1 and Amphotericin B flows logically from the art, in that TA1 has a known function in the art- stimulate hematopoiesis in bone marrow transplants and amphotericin B has a known function as an antifungal used in bone marrow transplants. Thus, the use of the two in combination flows logically from the teachings in the art.

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In response to applicant's argument that the art does not teach TA1 as an antifungal, and thus it is not obvious to combine with Amphotericin B, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Furthermore, it appears Applicant is improperly requiring the art to provide an explicit teaching of TA1 as an antifungal, effective against *Aspergillus*, to be used in making any rejection (§ 102 or § 103), however this is the improper standard, particularly since the claims recite a preventative aspect. Furthermore, it appears Applicant is only allowing for TA1 to be combined with Amphotericin B if they have the same purpose, akin to *In re Kerkhoven*, however, this too, is an improper standard, as there are multiple manners to show obviousness. A teaching that Amphotericin B was used as the antifungal does not, as Applicant asserts, teach away from the claimed invention, in that the examiner has different reason to combine. The teachings to combine TA1 and Amphotericin B for use bone marrow transplants flows logically from the art, and would not 'teach away' from TA1 being used. Again, as discussed above, TA1 has as an inherent property the antifungal activity claimed, and thus in the combination with Amphotericin- even if being used for a different purpose- is still being administered to a patient who is either immunocompromised (to prevent) or to the patient with *Aspergillus* (to treat). Such administration, even if administered/intended to induce hematopoiesis, alone or in the obvious combination with an antifungal, is still an obvious combination used to treat *Aspergillus* infections during bone marrow transplants.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 2, 4, 5, 7 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by CHRETIEN (US Patent 6,001,799).

Chretien teaches administration of TA1 to treat hepatitis C, which is an immuno-compromised patient (e.g. claim 3 and Example 6). Administration to any patient necessarily 'prevents' *Aspergillus* infections, including invasive Aspergillosis.

**Claims 1-5, 7, 8 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by GOLDSTEIN (US Patent 5,585,352).

Goldstein teaches administration of T $\alpha_1$  to treat septic shock (throughout) at doses of 400  $\mu$ g to 4 mg/kg (e.g. column 4, lines 23-32). Here, the lower limit of 400  $\mu$ g is the upper limit instantly claimed, and thus is anticipated. Further, as discussed above, administration to any patient necessarily 'prevents' *Aspergillus* infections, including invasive Aspergillosis.

**Claims 1-8 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by KNUTSEN (WO 98/35696 A1).

Knutsen teaches administration of thymosin  $\alpha_1$  to patients in need of bone marrow transplants in order to promote stem cell development (e.g. claims) at various dosages e.g. 100  $\mu$ g to 10 mg and 500  $\mu$ g to 5 mg. These patients, and those which are HIV positive, are immuno-compromised. Further, as discussed above, administration to any patient necessarily 'prevents' *Aspergillus* infections, including invasive Aspergillosis.

**Claims 1-8 and 12** are rejected under 35 U.S.C. 102(e) as being anticipated by RUDOLPH (US 2005/0049191 A1).

Rudolph teaches administration of T $\alpha_1$  to patients needing immune stimulation, including bone marrow transplant patients (e.g. ¶ [0015]) and teaches doses of 200  $\mu$ g/kg (e.g. ¶ [0020]).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over WINGARD (J.R. Wingard. Bone Marrow Transplantation (1997) 19, pages 343-347) in view of KNUTSEN, *supra*.

Wingard provides that amphotericin B is well known for treating *Aspergillus* infections related to bone marrow transplants (throughout). Kuntsen provides the teachings above that  $T\alpha_1$  is well known to be established for treating patients in need of bone marrow transplants. Thus, it would have been obvious that in treating bone marrow transplant patients, one would have coadministered  $T\alpha_1$  with amphotericin B in order to treat or prevent any fungal infection, including *Aspergillus* infections. One would reasonably expect the two drugs would function as they are known to in the art-  $T\alpha_1$  would stimulate hematopoiesis and amphotericin B would treat/prevent fungal infection.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654